



Biotechnology Regulatory Services Strategic Plan

(FY 2009 to FY 2014)

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United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
Riverdale, MD

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I. INTRODUCTION

The Biotechnology Regulatory Services (BRS) program of the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is responsible for regulating the importation, interstate movement, and field release of genetically engineered¹ (GE) organisms that may pose a plant pest risk. BRS exercises its authority under the Plant Protection Act through regulations in Title 7, Part 340 of the *Code of Federal Regulations* (7 CFR 340).

APHIS, as part of a coordinated Federal system, has regulated the agricultural biotechnology industry since 1987 and has authorized more than 10,000 field tests of GE organisms. To keep pace with rapidly evolving technology and to focus more Agency resources on biotechnology issues, APHIS created the BRS program in 2002. The BRS program combined units within the Agency with responsibility for regulating the products of modern biotechnology, except for Veterinary Services' Center for Veterinary Biologics, which regulates biotechnology-derived vaccines and diagnostic kits. As BRS reached its 5-year milestone, the program's leadership recognized the need to engage staff and stakeholders in documenting its strategic direction. Accordingly, BRS management invited all BRS employees to attend the initiation of the strategic planning effort at a conference held in October 2007.

This document records the organization's plan for the future – our vision of what we want BRS to become, the mission and values we share, the challenges facing us and how we will overcome them, and what we hope to achieve in the next 5 years. We will use this document to guide our internal planning and offer it to our partners to communicate and coordinate our joint efforts. In addition, we will provide this plan to stakeholder organizations, customers, and interested members of the public so that they may understand and learn about our efforts.

Vision

BRS will serve as a global leader in advancing a transparent and dynamic regulatory framework that anticipates and responds to the rapidly changing field of agricultural biotechnology, continually builds scientific capacity to accomplish this task, instills public trust, and collaborates with stakeholders.

¹ Genetic engineering is the process where one or more genes and other genetic elements from one or more organisms are inserted into the genetic material of a second organism or where genetic material of an organism is deleted or modified using recombinant DNA techniques. Engineering a gene or genes into an organism in this way allows researchers and developers to introduce, modify, or delete a particular trait or traits.

Mission

BRS' mission is to protect and enhance U.S. agricultural and natural resources using a dynamic, science-based regulatory framework to ensure the safe importation, interstate movement, and environmental release of GE organisms.

Values

We hold the following values in common and seek to demonstrate them as we carry out our mission:

- *Communication and Transparency*: We communicate clearly and foster an environment that facilitates open exchange of information and ideas.
- *Trustworthiness and Honesty*: We earn the confidence of others through the integrity of our actions.
- *Accountability*: We accept responsibility for our actions as individuals and as an Agency of the Federal Government.
- *Respect for Diverse Opinions*: We value and embrace diversity and treat everyone with dignity, respect, fairness, and compassion.
- *Balance and Consistency*: We consider the best available science when making decisions, while also acknowledging the importance of other factors.
- *Flexibility*: We adapt and respond effectively and efficiently to new and evolving circumstances.
- *Persistence and Perseverance*: We work steadily towards our goals, taking on challenges and doing our jobs to the best of our abilities.
- *Excellence*: We commit ourselves to high-quality performance and continuous timely improvement that produces outstanding results of lasting value.

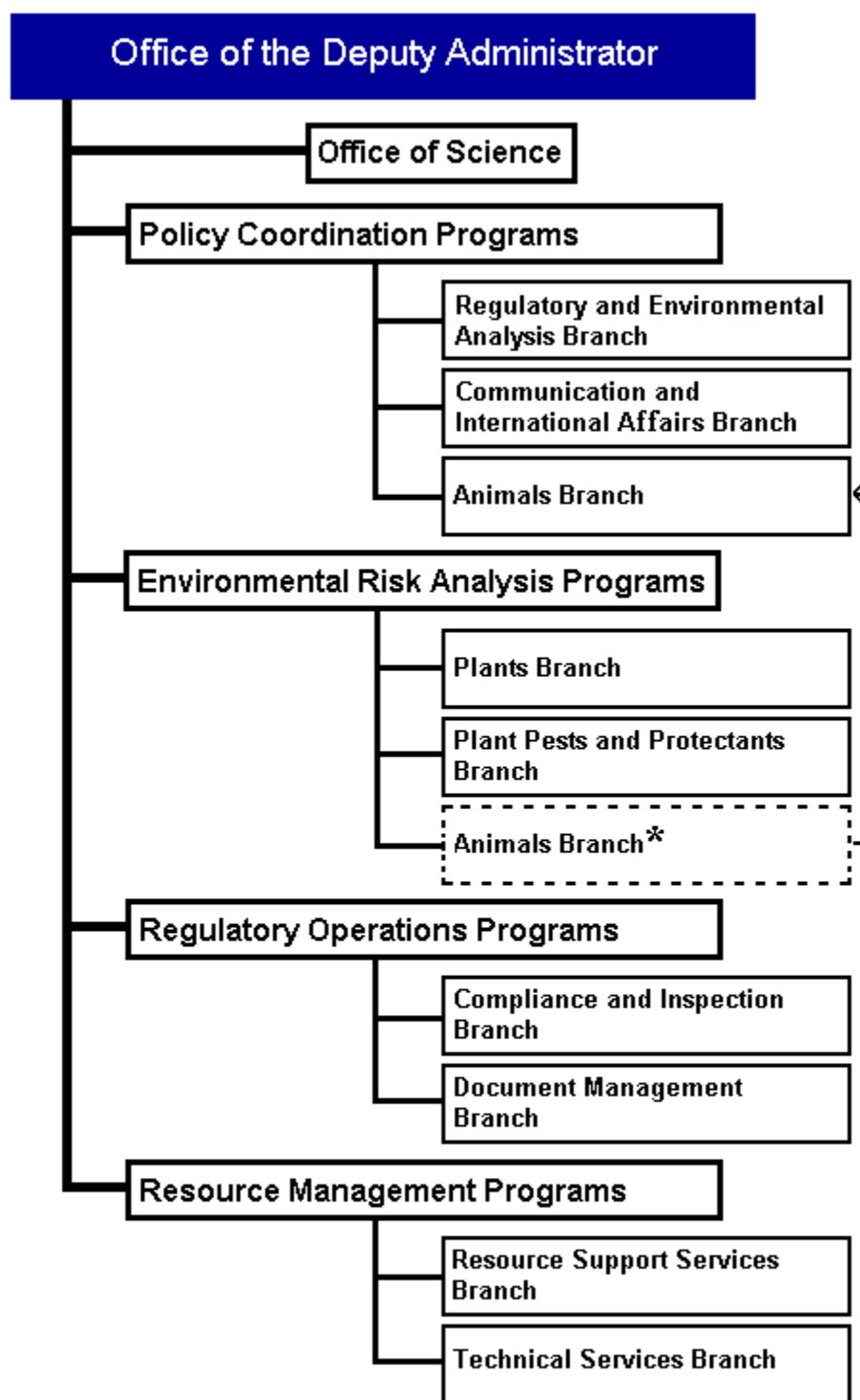
Organizational Structure

APHIS employs more than 8,500 people; the Agency's headquarters are located in Riverdale, Maryland, and Washington, D.C. BRS has four program units with several branches each, as shown in Figure 1. More information on BRS' organizational structure and functions is available on its website at:

http://www.aphis.usda.gov/biotechnology/about_prog_func.shtml.

Other useful information—including the Federal statutes and regulations under which BRS operates, as well as news and information, history, and guidance for researchers and developers of biotechnology—is available on the following Website:

http://www.aphis.usda.gov/biotechnology/brs_main.shtml.



*The Animals Branch, while under Policy Coordination Programs, also provides support to Environmental Risk Analysis Programs.

Figure 1: BRS' Organizational Chart

Core Functions

This document focuses on the organization's vision and strategic objectives over the next five years. BRS plans to meet these objectives through a combination of program enhancements and the continued delivery of its core functions. The delivery of these core functions is vital to providing the regulatory oversight of agricultural biotechnology. Select core functions include but are not limited to:

- Review and issue permits, notifications, and petitions.
- Develop international and domestic regulatory policy.
- Work with international standard-setting bodies to develop consistent standards.
- Carry out compliance assurance and enforcement activities including the inspection program.
- Participate in planned test exercises for agricultural and natural emergencies.
- Coordinate and assist with emergency related activities.
- Develop and coordinate communication and outreach strategies for domestic and international audiences.
- Promote transparency of the biotechnology regulatory process through guidance documents, fact sheets, and websites.
- Communicate with a full range of stakeholders including the regulated community, Federal and State government officials, and the public.
- Support employee development and training needs.
- Support succession and workforce planning.
- Enhance leadership/supervisory effectiveness.

Key Partners

BRS protects agricultural, natural, and other resources in cooperation with many partners, which include both domestic and international governmental, non-governmental, and private groups. BRS is committed to strengthening these partnerships and recognizes the unique contributions each makes to help anticipate and respond to the rapidly changing field of agricultural biotechnology.

BRS' develops its science-based regulatory framework in cooperation with two key Federal partners: the U.S. Environmental Protection Agency and the U.S. Department of Health and Human Services' Food and Drug Administration. BRS works with these agencies to coordinate responsibilities for regulatory oversight of agricultural biotechnology. The roles and responsibilities of these three agencies regarding the oversight of agricultural biotechnology products were first described in the Coordinated Framework for Regulation of Biotechnology (Office of Science and Technology Policy, 51 FR 23302, June 26, 1986).

BRS depends on its relationships with USDA partners to help meet many of its goals. This cross-agency relationship includes both support functions (such as administrative, financial, and legal services) as well as the strategies and means we employ to accomplish our objectives (such as science, research, and information management). Each of these efforts is a significant component of our work, and each plays a critical role in accomplishing our goals.

Recently, BRS has been forming new partnerships to perform its mission more effectively. In September 2007, the Secretary of Agriculture announced the formation of a new voluntary compliance assistance program, the Biotechnology Quality Management System (BQMS). Under this system, APHIS will partner with universities, small businesses, and large companies to develop sound management practices to enhance compliance with regulatory requirements for field trials and movements of GE organisms. BQMS will help the developers of biotechnology to prevent problems and become better environmental stewards by implementing best management practices for field testing and movement.

APHIS Strategic Plan

BRS' plan is consistent with the APHIS Strategic Plan for 2007 to 2012, which is available at http://www.aphis.usda.gov/about_aphis/strategic_plan.shtml. The priorities outlined in BRS' strategic plan support the following APHIS mission priorities, objectives, and management initiatives:

- ***Mission Priority 1:*** Strengthen our safeguarding system domestically and in other countries.
- ***Mission Priority 2:*** Strengthen emergency response preparedness.
- ***Mission Priority 3:*** Facilitate safe agricultural trade through effective management of sanitary and phytosanitary (SPS) issues.
- ***Organizational Priority 1:*** Value and invest in APHIS employees.
- ***Organizational Priority 2:*** Accomplish our mission through effective and efficient management of our programs.

II. KEY CHALLENGES

Challenge 1: Rapidly Changing Technology

Develop a regulatory framework and policies that anticipate rapidly changing technology.

The rapidly evolving field of biotechnology presents many new regulatory challenges. New applications of genetic engineering—novel traits, plant species such as perennials and trees, transgenic animals, and biofuel production—may pose unique environmental and public health issues. As the technology develops, applications for field trials include many new plant species, larger field sizes, new and novel traits and other factors which introduce new challenges for environmental analyses. BRS must develop processes and policies that address the challenges posed by these developments, and it also must create a policy and regulatory framework that anticipates, responds, and adapts quickly to advances in the technology in order to prevent the introduction of plant pest risks while making timely decisions. By strengthening relationships with academic researchers conducting biosafety research, BRS will enhance its efforts to complete high-quality risk assessments. Concurrently, BRS will implement state-of-the-art scientific principles consistently through transparent and effective guidance. Novel technologies may also require closer collaboration with other regulatory partners within APHIS and USDA, other Federal and State agencies working under different regulatory authorities, and ongoing collaboration with FDA and EPA—BRS' sister agencies under the coordinated framework.

Challenge 2: Balancing Diverse Interests

Operate predictably and transparently in an environment that is increasingly influenced by a wide range of factors.

In developing biotechnology policy, BRS takes into account a wide spectrum of social, economic, and political factors, in addition to natural, agricultural, and environmental sciences. It seeks out and acknowledges diverse internal and external interests and views, while basing decisions on sound science. Litigation and legislation may push BRS policy in new directions. Public debate about biotechnology remains polarized, with sectors of society and the agricultural industry rallying for or against new applications of the technology. Given the complex environment in which BRS operates, BRS must communicate clearly and consistently about the basis for the program's decisionmaking. Improved communication and outreach strategies will promote public trust, enhance transparency and predictability in the regulatory system for technology developers, and facilitate BRS' work in international standard setting and capacity building.

Challenge 3: Unforeseen Regulatory Incidents and Threats

Respond to unforeseen regulatory incidents and other threats to the Nation's agriculture and security.

Historically, BRS has identified and responded to unforeseen regulatory incidents through its compliance and inspection program. While the inspection program has been, and will continue to be, a valuable tool, BRS must expand to include other mechanisms such as auditing and BQMS and improve its ongoing monitoring efforts (currently, focused on inspections); its response to other time-sensitive and critical regulatory situations; and its response to a wide range of other government-wide emergency events. BRS needs to enhance its program-specific response capabilities by evaluating new means to assure compliance; developing innovative and adaptive strategies; establishing and enhancing partnerships; and building upon its infrastructure. BRS will develop a leadership role in government-wide emergency response efforts that require the unique skills and knowledge of the program's experts.

Challenge 4: Resource Limitations and Workforce Needs

Keep pace with the growth of the biotechnology industry and retain a highly qualified workforce, despite relatively stable resources.

The growing volume and complexity of our work challenges BRS to focus on being more efficient with existing resources. While it is difficult to predict the level of future appropriations, in recent years the BRS budget has been relatively flat. Assuming this trend continues, BRS must use its workforce even more efficiently and continue to improve and streamline work processes. Maintaining consistency between policies and procedures, as they are developed, will be keys to meeting the demands of the biotechnology industry and the public.

To attract and retain a highly qualified workforce, BRS must ensure that its employees are productively challenged and valued; assigned where their skills are most in demand; given opportunities for development; provided with the necessary tools and information; and receive high-quality leadership and administrative support.

III. STRATEGIC GOALS

BRS has identified four critical goals to successfully carry out its mission, meet its challenges, and achieve long-term success.

1. Strengthen Safeguarding
2. Strengthen Incident and Emergency Preparedness and Response
3. Improve Communication and Outreach
4. Create a Highly Effective Organization

Goal 1: Strengthen Safeguarding

To accomplish this goal, BRS must focus on both domestic and international activities that safeguard against risks from GE products developed in the United States or other countries. These activities include ongoing program functions such as the issuance of notifications and permits for the importation, interstate movement, and release of GE products and the determination of non-regulated status for these products. BRS must provide regulatory oversight that is commensurate with risk and regulations that can be applied to rapidly evolving technology. Once regulatory policy is developed, BRS must implement these policies through efficient and effective regulatory compliance and inspection operations and provide leadership internationally by promoting the adoption of science-based regulatory policies and standards overseas.

Objective 1.1 Develop Regulatory Policies that are Timely and Commensurate with Risk.

To meet this objective, BRS is revising the plant regulations in 7 CFR 340 to include plant pest and noxious weed authorities. In addition, working with the Department of Health and Human Services' Food and Drug Administration, the Environmental Protection Agency and other USDA Agencies, BRS is involved in the development of a framework for regulating GE animals including GE insect pests that may pose a risk to animal and plant health.

BRS promotes a rigorous, science-based risk assessment framework. Timely guidance documents, based on the best available scientific data and sound policies, are the baseline of this framework. Specifically, BRS will:

- Develop and/or revise regulations that are commensurate with risk and that reflect our years of regulatory experience;
- Improve the timeliness and efficacy of policymaking, risk assessments, and decisions;
- Provide appropriate and timely guidance; and
- Improve the adaptability of policies to anticipate the evolving needs of the regulated community..

Objective 1.2 Enhance the Regulatory Framework through Better Regulatory Operations.

To strengthen domestic agriculture and protect natural resources from risks associated with field testing of regulated GE organisms, BRS will:

- Enhance its compliance assistance and outreach activities;

- Expand and diversify its compliance inspection program, and surveillance and monitoring activities (such as quality management and auditing functions) for field testing and movement; and
- Identify and adopt best practices and enhance automation for internal BRS procedures.

Objective 1.3 Build International Regulatory Approaches and Capacity and Provide Technical Expertise.

To protect domestic agriculture and natural resources from risks associated with GE organisms, BRS will continue to play a significant role in the international biotechnology community. This means BRS will:

- Support the development and implementation of international standards and regulatory approaches. As adoption of GE crops increases worldwide, BRS anticipates a rapid increase in requests to import GE seeds and commodities developed in other countries. By supporting international standards and consistent regulatory approaches, BRS increases the likelihood that other countries developing GE products are using rigorous, science based regulatory approaches, reducing risks to U.S. crops and the environment.
- Build international regulatory capacity and understanding of biotechnology in developing countries. By building regulatory capacity in other countries, BRS can foster the safe development of agricultural GE products in these countries and promote increased public confidence in GE products worldwide. Increased understanding and capacity to assess the safety of biotechnology products can also lead to support for U.S. positions in international discussions with respect to agricultural biotechnology and can reduce barriers to trade in U.S. agricultural products.
- Provide technical support for the resolution of import and export barriers. Biotechnology is increasingly included in discussions of trade agreements or in consideration of third countries' World Trade Organization accession. BRS provides technical expertise to support a science and risk-based approach to safeguard the environment.

Goal 2: Strengthen Incident and Emergency Preparedness and Response

In recent years, BRS has responded to a number of regulatory events. There is also a growing awareness that BRS must assist in APHIS' mission to enhance emergency management and meet commitments on a wide range of other Agency, USDA, and Federal emergency events.

BRS will continue to work openly and cooperatively to protect America's agriculture and environment through enhanced incident management and response capacity. To reach this goal, BRS will develop an infrastructure for managing and responding to emergency events so that important activities (i.e., environmental risk assessments, permitting, etc.) can proceed with minimal interruption, even during an emergency.

Objective 2.1 Respond effectively to emergencies, regulatory events, and compliance incidents.

To meet this objective, BRS will develop effective approaches and tools to improve its response to emergencies, regulatory events, and compliance incidents. For example, BRS will require key employees to participate in Incident Command System (ICS) training and other emergency management training and will develop test exercises to measure the program's emergency preparedness and response capabilities. BRS will also explore the use of GIS-based surveillance tools and other technology to more effectively respond to accidents and extreme climatic events involving regulated activities.

Objective 2.2 Develop partnerships and identify command and coordination roles and responsibilities that are consistent with APHIS' Emergency Mobilization Guide.

To meet this objective, BRS will develop partnerships and identify command and coordination roles and responsibilities necessary to respond to a breadth of emergencies. For example, BRS will include an emergency response clause in its Memorandum of Understanding (MOU) with APHIS' Plant Protection and Quarantine (PPQ). BRS will implement MOUs with USDA's Agricultural Marketing Service and Grain Inspection, Packers and Stockyards Administration related to emergency activities as they pertain to the identification of regulated plant material.

Objective 2.3 Develop and disseminate information (externally and internally) on emergency management and response functions within BRS.

To meet this objective, BRS will develop and disseminate information about emergency management and response functions to the regulated community, its partners, and the public. For example, BRS will use the APHIS Emergency Mobilization Guide to inform its employees of their roles and responsibilities in biotechnology emergency events and other Agency emergencies.

Goal 3: Improve Communication and Outreach

BRS will develop and implement effective communication and outreach strategies. Clearly and consistently communicating regulatory policy and decisionmaking will increase the transparency of the regulatory system, enhance compliance of the

regulated community, and improve public confidence. By meeting this goal, BRS will address all of the key challenges identified.

Objective 3.1 Build internal communication systems that are inclusive, consistent, and well coordinated.

Effective internal communication is a necessary component of strong external communication, which leads to message consistency. BRS will improve the processes it uses to make and implement policy decisions by improving communication between BRS management and staff, among organizational divisions within BRS, and with other APHIS programs. BRS must continue to develop and implement standard operating procedures, effective staff training, and regular updates so that its policies and procedures are understood and applied consistently across the program.

Objective 3.2 Improve communications with domestic stakeholders including Federal and State agencies, tribal nations, non-government organizations, and members of the regulated community.

As regulatory issues become increasingly complex and cross over a wide range of regulatory authorities, BRS must expand communication and coordination with other Federal, State, and tribal agencies. This effort will help applicants improve compliance with BRS regulations while they are conducting field tests and movements. It will also help the other Federal, State, and tribal agencies to assist and coordinate with APHIS on enforcement issues.

BRS' highest outreach priority is the consistent, timely, and widespread communication of its policies to those most directly affected: the regulated community, the States, and Federally Recognized Tribes. BRS will continue in a timely manner to develop and refine guidance materials and other written documents that clearly articulate BRS policy. Development of new guidance documents will be particularly critical as BRS implements revisions to 7 CFR 340. Additionally, BRS will identify segments of the stakeholder community, such as non-government organizations and academics or small businesses, and develop communication strategies to reach each of them more effectively. Similarly, BRS will develop novel strategies, such as BQMS, that build compliance-enhancing partnerships with the regulated community.

Objective 3.3 Determine and use the most critical key communication strategies when working with international partners.

Outreach to a variety of international stakeholders—including developing countries, key trading partners, and international organizations involved in biotechnology policy and research—will continue to be important for BRS. As BRS develops and implements revisions to 7 CFR 340, the program must closely collaborate and communicate with foreign regulators through multilateral interactions, regional

groups, and standard setting bodies to ensure a global consensus on what constitutes safety. Given increasing demands for international capacity building, BRS will coordinate with other programs and agencies—such as the International Technical and Regulatory Capacity Building Center and the Foreign Agricultural Service (FAS)—to set priorities in order to use its resources most effectively. These interactions will provide new opportunities for BRS to expand international outreach. For example, BRS will work more closely with the Agency's International Services (IS) program and FAS to prepare for international meetings that address biotechnology. Also, BRS will continue to expand the technical support it provides to FAS to help resolve agricultural trade barriers involving biotechnology.

Goal 4: Create a Highly Effective Organization

BRS recognizes that it must effectively manage its critical resources to successfully carry out its mission and to accomplish the objectives of its three other mission goals (strengthen safeguarding, strengthen incident and emergency preparedness and response, and improve communications and outreach). With an effective management system in place, BRS will meet its mission objectives.

Objective 4.1 Attract and retain a highly-qualified workforce.

BRS must first ensure all employees have the necessary knowledge, skills, and tools. BRS will emphasize succession and workforce planning. Additionally, BRS will continue to explore and develop recruitment strategies, including recruiting employees in under-represented areas. BRS will recruit and hire managers and will ensure that these managers have the requisite abilities to effectively support employees. BRS will provide its current managers with the best tools and information to accomplish program goals and objectives, build diversity, create a positive work environment, deliver great customer service, and encourage employees to communicate and collaborate more effectively.

BRS must also develop administrative policies and processes that are fair and flexible to help employees balance home and work lives. Finally, employees must clearly understand their performance expectations, be held accountable, and be recognized for excellent performance.

Objective 4.2 Ensure that budgetary resources are adequate and properly aligned with projected workload and priorities.

Another critical resource for BRS is its budget. BRS will request funds for new and existing staff so that resources are properly aligned with projected workload and priorities and are allocated and accounted for in the status of funds process. Budget requests will address emerging issues and trends, will be distributed according to workloads across program divisions, and will be spent appropriately using transparent reporting and monitoring processes, such as the status of funds reports.

Objective 4.3 Ensure that the information technology needs of the organization are proactively identified and addressed.

BRS' information database systems are critical. Without high-quality systems, the best policies, procedures, and scientific data cannot be effectively shared with or used by the scientific community, the public, or regulated entities. BRS will develop a comprehensive information technology (IT) strategic plan, assuring that the program's mission will not be compromised by IT gaps.

Objective 4.4 Document work management systems, procedures, and policies.

Additionally, BRS must ensure that document and work management systems (including standard operating procedures) are sound, promote consistency, measure results and outcomes, and maintain a high level of quality control and accountability. BRS will conduct internal audits and work-process improvement reviews to help refine these systems.

Objective 4.5 Ensure timely, coordinated, transparent, and effective prevention and response to regulatory decisionmaking challenges.

As the adoption of agricultural biotechnology products increases, stakeholders have expressed concerns about a growing number of issues related to the safeguarding system. As a result, BRS anticipates greater scrutiny and more frequent challenges of its regulatory decisionmaking. As a result of this scrutiny, BRS will develop new and innovative approaches to effectively prepare for and respond to lawsuits, enhance compliance with improved administrative record requirements, and ensure that its procedures comply with appropriate Federal regulations. BRS will also improve communications with stakeholders prior to significant regulatory determinations to address concerns earlier in the process. BRS will also implement strategies to minimize or prevent challenges.

IV. CONCLUSION

The four strategic goals are instrumental in leading BRS forward for the next several years. We will continue to support the goals of APHIS and USDA through our revised regulatory framework and improvements to our regulatory operations. In doing so, we will continue to value and invest in our employees, create a highly effective and efficient organization, and communicate on a regular basis with our international colleagues, domestic partners, stakeholders and the general public.